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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,503	03/30/2004	Henry A. Lardy	302.1	6454

26551 7590 03/26/2007  
HOLLIS-EDEN PHARMACEUTICALS, INC.  
4435 EASTGATE MALL  
SUITE 400  
SAN DIEGO, CA 92121

EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/814,503

Applicant(s)

LARDY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 54-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **First Office Action on the Merits**

#### ***Election/Restrictions***

1. Applicant's election of Group I and the compound found in claim 63 is noted. It is noted that the claims will be examined according to MPEP § 803.02.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 54-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

- (a) The instant claims recite compound(s) of formulae IA or IB, wherein the compound the compound "comprises" various dienes. However, the use of the term "comprises" implies additional bonds are possible. For example, claim 58 is limited to 1,3- and 1,5-dienes but the structure of formula IB includes additional bonds in other positions, i.e., 4-, 5-, 7- and 15-. For the purpose of art rejection and based on the disclosure, the examiner assumes the compounds consist of one of said dienes.
- (b) Claim 54, in the definition of G, the definition of  $=CR^3$  and  $-CR^3R^4$  are unclear. The instant claim recites, " $R^3$  and  $R^4$  are  $-H$  or one of  $R^3$  and  $R^4$  is  $-H$  and the other is  $-OH$  or substituted or unsubstituted lower alkoxy". The second definition of  $R^3/R^4$  appears to

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refer to " $-CR^3R^4-$ " since one of  $R^3/R^4$  has to be hydrogen and the other a hydroxyl or an alkoxy group. However, in the definition of  $R^3$ , claim 55, recites  $-H$ ,  $-OH$  or alkoxy.

(c) Claim 54 recites compounds having a "3, 16-diene" within the steroid moiety.

However, based on the definition of A in formula IA, the carbon atom at the 17-position has four bonds thus, a 16(17) bond is not feasible since said bond would result a carbon atom with five bonds instead of the normal four bonds.

(d) Claim 60 recites a compound with a 17-oxo group. Parent claim 54 is limited to compounds having an alkyne and a hydroxyl or alkoxy group and does not encompass 17-oxo derivatives of the claimed compound.

(e) Claim 62 defines  $R^9$  as  $-H$ , however, the definition of said group in parent claim 54 does not include hydrogen.

(f) Claim 63 recites a compound having  $17\alpha$ -alkyne and  $17\beta$ -hydroxyl groups. The instant claim is dependent on claim 62 that recites compounds having only a 17-alkyne group.

Note: The examiner opted to make the above rejection of record because of the nature and variety 112, second issues.


#### ***Telephone Inquiry***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
March 19, 2007